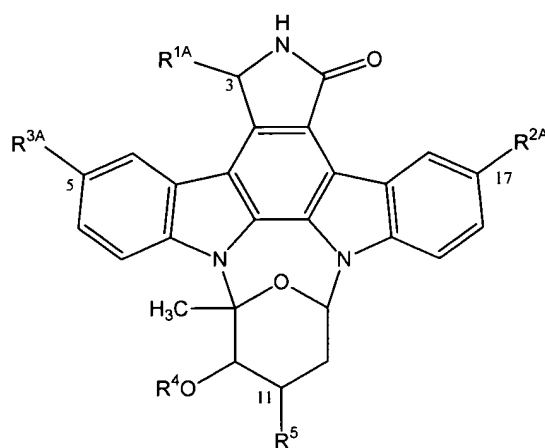


a.) Amendments to the Claims

1. (Cancelled)
2. (Previously Presented) A compound of formula (IA):



(IA)

wherein

$R^{1A}$  represents hydroxy or lower alkoxy;

$R^{2A}$  represents hydrogen, hydroxy, halogen, formyl, nitro, amino,

$COR^{6A1}$  (wherein  $R^{6A1}$  represents substituted or unsubstituted lower alkyl, hydroxy, or substituted or unsubstituted lower alkoxy),  $OR^{14A1}$  (wherein  $R^{14A1}$  represents substituted or unsubstituted lower alkyl), substituted or unsubstituted lower alkyl, substituted or unsubstituted lower alkenyl, substituted or unsubstituted lower alkadienyl, substituted or unsubstituted lower alkynyl, substituted or unsubstituted aryl, a substituted or unsubstituted heterocyclic group,  $COR^{6A3}$  (wherein  $R^{6A3}$  has the same meaning as defined for  $R^{6A2}$ ),  $NR^{11A2}R^{12A2}$  (wherein  $R^{11A2}$  and  $R^{12A2}$  have the same meaning as defined for  $R^{11A1}$  and  $R^{12A1}$ , respectively), or  $OR^{14A3}$  (wherein  $R^{14A3}$  has the same meaning as defined for  $R^{14A2}$ );

when  $R^{2A}$  represents hydrogen, hydroxymethyl, hydroxy, halogen, formyl, nitro, amino,  $COR^{6A1}$  (wherein  $R^{6A1}$  represents substituted or unsubstituted lower

alkyl, hydroxy, or substituted or unsubstituted lower alkoxy), or  $OR^{14A1}$  (wherein  $R^{14A1}$  represents substituted or unsubstituted lower alkyl),

then  $R^{3A}$  represents substituted or unsubstituted lower alkyl (other than hydroxymethyl), substituted or unsubstituted lower alkenyl, substituted or unsubstituted lower alkadienyl, substituted or unsubstituted lower alkynyl, substituted or unsubstituted aryl, a substituted or unsubstituted heterocyclic group,  $COR^{6A2}$  {wherein  $R^{6A2}$  represents substituted or unsubstituted aryl, a substituted or unsubstituted heterocyclic group,  $NR^{7A1}R^{8A1}$  (wherein  $R^{7A1}$  and  $R^{8A1}$  independently represent hydrogen, substituted or unsubstituted lower alkyl, substituted or unsubstituted lower alkenyl, cycloalkyl having 3 to 6 carbon atoms, substituted or unsubstituted aryl, or a substituted or unsubstituted heterocyclic group, or are combined with their adjacent N to form a substituted or unsubstituted heterocyclic group that may contain an oxygen atom, a sulfur atom, or another nitrogen atom),  $OR^{9A1}$  (wherein  $R^{9A1}$  represents substituted or unsubstituted lower alkenyl, cycloalkyl having 3 to 6 carbon atoms, or substituted or unsubstituted aryl), or  $SR^{10A1}$  (wherein  $R^{10A1}$  represents substituted or unsubstituted lower alkyl, or substituted or unsubstituted aryl) },  $NR^{11A1}R^{12A1}$  {wherein  $R^{11A1}$  and  $R^{12A1}$  independently represent hydrogen, substituted or unsubstituted lower alkyl, substituted or unsubstituted lower alkenyl, cycloalkyl having 3 to 6 carbon atoms,  $COR^{13A}$  [wherein  $R^{13A}$  represents substituted or unsubstituted lower alkyl, substituted or unsubstituted lower alkenyl, lower alkoxy carbonyl, substituted or unsubstituted aryl, a substituted or unsubstituted heterocyclic group,  $OR^{9A}$  (wherein  $R^{9A}$  represents hydrogen, substituted or unsubstituted lower alkyl, substituted or unsubstituted lower alkenyl, cycloalkyl having 3 to 6 carbon atoms, or substituted or unsubstituted aryl),  $NR^{7A}R^{8A}$  (wherein  $R^{7A}$  and  $R^{8A}$  have the same meaning as defined for  $R^{7A1}$  and  $R^{8A1}$ , respectively)],  $CSR^{13A}$ ,  $SO_2R^{13B}$  (wherein  $R^{13B}$  has the same meaning as defined for  $R^{13A}$ ), or a group derived from an amino acid (wherein a hydroxyl group in a carboxyl group is excluded from the amino acid and a functional group

in the amino acid may be protected with a protective group), with the proviso that  $R^{11A1}$  and  $R^{12A1}$  are not simultaneously hydrogen}, or  $OR^{14A2}$  {wherein  $R^{14A2}$  represents substituted or unsubstituted lower alkenyl, cycloalkyl having 3 to 6 carbon atoms, substituted or unsubstituted lower alkanoyl, substituted or unsubstituted aroyl, or  $CONR^{7B1}R^{8B1}$  (wherein  $R^{7B1}$  and  $R^{8B1}$  have the same meanings as defined for  $R^{7A1}$  and  $R^{8A1}$ , respectively))};

when  $R^{2A}$  represents lower alkyl, substituted lower alkyl (other than hydroxymethyl), substituted or unsubstituted lower alkenyl, substituted or unsubstituted lower alkadienyl, substituted or unsubstituted lower alkynyl, substituted or unsubstituted aryl, a substituted or unsubstituted heterocyclic group,  $COR^{6A3}$  (wherein  $R^{6A3}$  has the same meaning as defined for  $R^{6A2}$ ),  $NR^{11A2}R^{12A2}$  (wherein  $R^{11A2}$  and  $R^{12A2}$  have the same meanings as defined for  $R^{11A1}$  and  $R^{12A1}$ , respectively), or  $OR^{14A3}$ ,

then  $R^{3A}$  represents substituted or unsubstituted lower alkyl, substituted or unsubstituted lower alkenyl, substituted or unsubstituted lower alkadienyl, substituted or unsubstituted lower alkynyl, substituted or unsubstituted aryl, a substituted or unsubstituted heterocyclic group, halogen, nitro, formyl,  $COR^{6A4}$  [wherein  $R^{6A4}$  represents substituted or unsubstituted lower alkyl, substituted or unsubstituted aryl, a substituted or unsubstituted heterocyclic group,  $NR^{7A2}R^{8A2}$  {wherein  $R^{7A2}$  and  $R^{8A2}$  have the same meanings as defined for  $R^{7A1}$  and  $R^{8A1}$ , respectively},  $OR^{9A2}$  (wherein  $R^{9A2}$  has the same meaning as defined for  $R^{9A}$ ), or  $SR^{10A2}$  (wherein  $R^{10A2}$  has the same meaning as defined for  $R^{10A1}$ )],  $NR^{11A3}R^{12A3}$  (wherein  $R^{11A3}$  and  $R^{12A3}$  have the same meaning as defined for  $R^{11A1}$  and  $R^{12A1}$ , respectively), or  $OR^{14A4}$  (wherein  $R^{14A4}$  represents hydrogen, substituted or unsubstituted lower alkyl, substituted or unsubstituted lower alkenyl, cycloalkyl having 3 to 6 carbon atoms, substituted or unsubstituted lower alkanoyl, substituted or unsubstituted aroyl, or  $CONR^{7A1}R^{8A1}$ );

$R^4$  represents hydrogen, or substituted or unsubstituted lower alkyl;

and

$R^5$  represents  $NR^{11A}R^{12A}$ ; (wherein  $R^{11A}$  and  $R^{12A}$  have the same meaning as defined for  $R^{11}$  and  $R^{12}$ , respectively;

wherein the substituents in the substituted lower alkyl and substituted lower alkoxy are independently selected from the group consisting of halogen, carboxy, lower alkoxycarbonyl, lower alkanoyl, substituted or unsubstituted aryl, a substituted or unsubstituted heterocyclic group,  $CONR^{15}R^{16}$  (wherein  $R^{15}$  and  $R^{16}$  independently represent hydrogen, hydroxy, aralkyl, lower alkyl, lower alkenyl, substituted or unsubstituted aryl, a substituted or unsubstituted heterocyclic group, or are combined with their adjacent N to form a heterocyclic group),  $NR^{17}R^{18}$  {wherein  $R^{17}$  and  $R^{18}$  independently represent hydrogen, lower alkyl, lower alkenyl, lower alkanoyl, aroyl, substituted or unsubstituted aryl, a substituted or unsubstituted heterocyclic group, substituted lower alkyl [the substituted lower alkyl is replaced by at least one of hydroxy, lower alkoxy,  $O(CH_2CH_2O)_nR^{19}$  (wherein n is an integer of 1 to 15, and  $R^{19}$  is lower alkyl), oxo, carboxy, lower alkoxycarbonyl, substituted or unsubstituted aryl, a substituted or unsubstituted heterocyclic group,  $CONR^{15A}R^{16A}$  (wherein  $R^{15A}$  and  $R^{16A}$  have the same meaning as defined for  $R^{15}$  and  $R^{16}$ , respectively), amino, lower alkylamino, and di(lower alkyl)amino], cycloalkyl having 3 to 6 carbon atoms, or aralkyloxycarbonyl, are combined with their adjacent N to form a substituted or unsubstituted heterocyclic group},  $N^+R^{20}R^{21}R^{22}X^-$  [wherein  $R^{20}$  and  $R^{21}$  independently represent lower alkyl, or are combined with their adjacent N to form a heterocyclic group,  $R^{22}$  is lower alkyl, and X is an atom of chlorine, bromine or iodine],  $OR^{23}$  {wherein  $R^{23}$  represents hydrogen, lower alkyl, lower alkanoyl, lower alkyl [which is substituted with at least one of hydroxy, lower alkoxy,  $O(CH_2CH_2O)_{nA}R^{19A}$  (wherein  $nA$  is an integer of 1 to 15, and  $R^{19A}$  is lower alkyl), oxo, carboxy, lower alkoxycarbonyl, substituted or unsubstituted aryl, a substituted or

unsubstituted heterocyclic group,  $\text{CONR}^{15\text{B}}\text{R}^{16\text{B}}$  (wherein  $\text{R}^{15\text{B}}$  and  $\text{R}^{16\text{B}}$  have the same meaning as defined for  $\text{R}^{15}$  and  $\text{R}^{16}$ , respectively), amino, lower alkylamino, and di(lower alkyl)amino], substituted or unsubstituted aryl, and a substituted or unsubstituted heterocyclic group},  $\text{SR}^{23\text{A}}$  (wherein  $\text{R}^{23\text{A}}$  has the same meaning as defined for  $\text{R}^{23}$ ) and  $\text{SO}_2\text{R}^{23\text{B}}$  (wherein  $\text{R}^{23\text{B}}$  is lower alkyl);

the substituents for lower alkenyl, lower alkadienyl and lower alkynyl include oxo in addition to the substituents permitted for lower alkyl;

the substituents for lower alkanoyl are independently selected from the group consisting of halogen and  $\text{NR}^{17\text{A}}\text{R}^{18\text{A}}$  (wherein  $\text{R}^{17\text{A}}$  and  $\text{R}^{18\text{A}}$  have the same meaning as defined for  $\text{R}^{17}$  and  $\text{R}^{18}$ , respectively);

the substituents for aryl and aroyl are independently selected from the group consisting of halogen, lower alkyl (optionally substituted with halogen, oxo, carboxy, lower alkoxy, carbonyl, amino, lower alkylamino, di (lower alkyl) amino, hydroxy or lower alkoxy), nitro, hydroxy, lower alkoxy, amino, lower alkylamino, di(lower alkyl)amino, lower alkanoyl and cyano; and

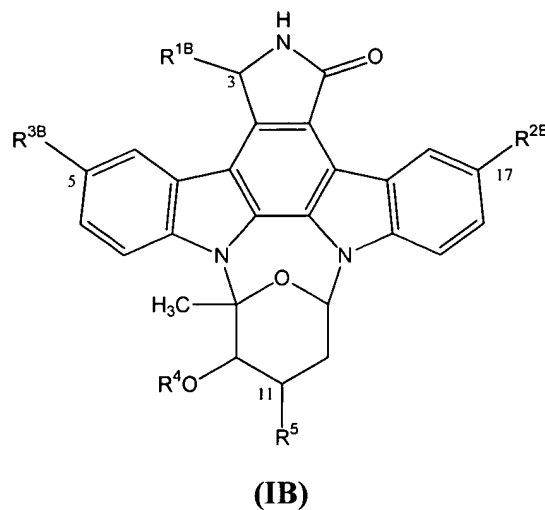
the substituents for the heterocyclic group and the heterocyclic group formed using the adjacent N include oxo in addition to the substituents permitted for aryl and aroyl; and

wherein the heterocyclic group is selected from the group consisting of pyrrolidinyl, imidazolidinyl, piperidinyl, morpholinyl, thiomorpholinyl, piperidino, morpholino, piperadinyl, furyl, thienyl, pyrrolyl, imidazolyl, triazolyl, oxazolyl, thiazolyl, pyridyl, pyrimidinyl, indolyl, quinolyl, isoquinolyl and quinazolinyl; and

the heterocyclic group formed together using the adjacent N is selected from the group consisting of pyrrolidinyl, morpholino, thiomorpholino, N-methylpiperadinyl, pyrazolidinyl, piperidino, piperadinyl, homopiperadinyl, indolyl and isoindolyl;

or a pharmaceutically acceptable salt thereof.

3. (Previously Presented) A compound of formula (IB):



wherein

R<sup>1B</sup> represents hydroxy or lower alkoxy;

R<sup>2B</sup> and R<sup>3B</sup> independently represent substituted or unsubstituted lower alkyl, substituted or unsubstituted lower alkenyl, substituted or unsubstituted lower alkadienyl, substituted or unsubstituted lower alkynyl, substituted or unsubstituted aryl, a substituted or unsubstituted heterocyclic group, nitro, formyl, COR<sup>6</sup> <wherein R<sup>6</sup> represents substituted lower alkyl, substituted or unsubstituted aryl, a substituted or unsubstituted heterocyclic group, NR<sup>7</sup>R<sup>8</sup> {wherein R<sup>7</sup> and R<sup>8</sup> independently represent hydrogen, substituted or unsubstituted lower alkyl, substituted or unsubstituted lower alkenyl, cycloalkyl having 3 to 6 carbon atoms, substituted or unsubstituted aryl, or a substituted or unsubstituted heterocyclic group, or are combined with their adjacent N to form a substituted or unsubstituted heterocyclic group (which may contain an oxygen atom, a sulfur atom, or another nitrogen atom)}}, OR<sup>9</sup> (wherein R<sup>9</sup> represents hydrogen,

substituted or unsubstituted lower alkyl, substituted or unsubstituted lower alkenyl, cycloalkyl having 3 to 6 carbon atoms, or substituted or unsubstituted aryl), or  $SR^{10}$  (wherein  $R^{10}$  represents substituted or unsubstituted lower alkyl, or substituted or unsubstituted aryl)  $>$ ,  $NR^{11}R^{12}$  (wherein  $R^{11}$  and  $R^{12}$  independently represent hydrogen, substituted or unsubstituted lower alkyl, substituted or unsubstituted lower alkenyl, cycloalkyl having 3 to 6 carbon atoms,  $COR^{13}$  {wherein  $R^{13}$  represents substituted or unsubstituted lower alkyl, substituted or unsubstituted lower alkenyl, lower alkoxy carbonyl, substituted or unsubstituted aryl, a substituted or unsubstituted heterocyclic group,  $OR^{9A}$  (wherein  $R^{9A}$  has the same meaning as defined for  $R^9$ ),  $NR^{7A}R^{8A}$  (wherein  $R^{7A}$  and  $R^{8A}$  have the same meanings as defined for  $R^7$  and  $R^8$ , respectively)},  $CSR^{13A}$  (wherein  $R^{13A}$  has the same meaning as defined for  $R^{13}$ ),  $SO_2R^{13B}$  (wherein  $R^{13B}$  has the same meaning as defined for  $R^{13}$ ), or a group derived from an amino acid (wherein a hydroxyl group in a carboxyl group is excluded from the amino acid and a functional group in the amino acid may be protected with a protective group)  $>$ , or  $OR^{14}$  {wherein  $R^{14}$  represents substituted lower alkyl, substituted or unsubstituted lower alkenyl, cycloalkyl having 3 to 6 carbon atoms, substituted or unsubstituted lower alkanoyl, substituted or unsubstituted aroyl, or  $CONR^{7B}R^{8B}$  (wherein  $R^{7B}$  and  $R^{8B}$  have the same meaning as defined for  $R^7$  and  $R^8$ , respectively)};

$R^4$  represents hydrogen, or substituted or unsubstituted lower alkyl;

and

$R^5$  represents  $NR^{11A}R^{12A}$  (wherein  $R^{11A}$  and  $R^{12A}$  have the same meaning as defined for  $R^{11}$  and  $R^{12}$ , respectively);

wherein the substituents in the lower alkyl and lower alkoxy are independently selected from the group consisting of halogen, carboxy, lower alkoxy carbonyl, lower alkanoyl, substituted or unsubstituted aryl, a substituted or unsubstituted heterocyclic group,  $CONR^{15}R^{16}$  [wherein  $R^{15}$  and  $R^{16}$  independently represent

hydrogen, hydroxy, aralkyl, lower alkyl, lower alkenyl, substituted or unsubstituted aryl, a substituted or unsubstituted heterocyclic group, or are combined with their adjacent N to form a heterocyclic group],  $\text{NR}^{17}\text{NR}^{18}$  (wherein  $\text{R}^{17}$  and  $\text{R}^{18}$  independently represent hydrogen, lower alkyl, lower alkenyl, lower alkanoyl, aroyl, substituted or unsubstituted aryl, a substituted or unsubstituted heterocyclic group, substituted lower alkyl [which is substituted with at least one of hydroxy, lower alkoxy,  $\text{O}(\text{CH}_2\text{CH}_2\text{O})_n\text{R}^{19}$  (wherein  $n$  is an integer of 1 to 15, and  $\text{R}^{19}$  is lower alkyl), oxo, carboxy, lower alkoxycarbonyl, substituted or unsubstituted aryl, a substituted or unsubstituted heterocyclic group,  $\text{CONR}^{15A}\text{R}^{16A}$  (wherein  $\text{R}^{15A}$  and  $\text{R}^{16A}$  have the same meaning as defined for  $\text{R}^{15}$  and  $\text{R}^{16}$ , respectively), amino, lower alkylamino, and di(lower alkyl)amino], cycloalkyl having 3 to 6 carbon atoms, or aralkyloxycarbonyl, or are combined with their adjacent N to form a substituted or unsubstituted heterocyclic group},  $\text{N}^+\text{R}^{20}\text{R}^{21}\text{R}^{22}\text{X}^-$  [wherein  $\text{R}^{20}$  and  $\text{R}^{21}$  independently represent lower alkyl, or are combined with their adjacent N to form a heterocyclic group,  $\text{R}^{22}$  is lower alkyl, and  $\text{X}$  is an atom of chlorine, bromine or iodine],  $\text{OR}^{23}$  {wherein  $\text{R}^{23}$  represents hydrogen, lower alkyl, lower alkanoyl, substituted lower alkyl [which is substituted with at least one of hydroxy, lower alkoxy,  $\text{O}(\text{CH}_2\text{CH}_2\text{O})_{nA}\text{R}^{19A}$  (wherein  $nA$  is an integer of 1 to 15, and  $\text{R}^{19A}$  is lower alkyl), oxo, carboxy, lower alkoxycarbonyl, substituted or unsubstituted aryl, a substituted or unsubstituted heterocyclic group,  $\text{CONR}^{15B}\text{R}^{16B}$  (wherein  $\text{R}^{15B}$  and  $\text{R}^{16B}$  have the same meaning as defined for  $\text{R}^{15}$  and  $\text{R}^{16}$ , respectively), amino, lower alkylamino, and di(lower alkyl)amino], substituted or unsubstituted aryl, and a substituted or unsubstituted heterocyclic group,  $\text{SR}^{23A}$  (wherein  $\text{R}^{23A}$  has the same meaning as defined for  $\text{R}^{23}$ ) and  $\text{SO}_2\text{R}^{23B}$  (wherein  $\text{R}^{23B}$  is lower alkyl);

the substituents for the lower alkenyl, lower alkadienyl and lower alkynyl include oxo in addition to the substituents in the lower alkyl;



the substituents for the lower alkanoyl are independently selected from the group consisting of halogen and  $\text{NR}^{17\text{A}}\text{R}^{18\text{A}}$  (wherein  $\text{R}^{17\text{A}}$  and  $\text{R}^{18\text{A}}$  have the same meaning as defined for  $\text{R}^{17}$  and  $\text{R}^{18}$ , respectively);

the substituents for the aryl and aroyl are independently selected from the group consisting of halogen, lower alkyl (optionally substituted with halogen, oxo, carboxy, lower alkoxy, carbonyl, amino, lower alkylamino, di (lower alkyl) amino, hydroxy or lower alkoxy), nitro, hydroxy, lower alkoxy, amino, lower alkylamino, di(lower alkyl)amino, lower alkanoyl and cyano; and

the substituents for the heterocyclic group and the heterocyclic group formed to using the adjacent N include oxo in addition to the substituents permitted for aryl and aroyl; and

wherein the heterocyclic group is selected from the group consisting of pyrrolidinyl, imidazolidinyl, piperidinyl, morpholinyl, thiomorpholinyl, piperidino, morpholino, piperadinyl, furyl, thienyl, pyrrolyl, imidazolyl, triazolyl, oxazolyl, thiazolyl, pyridyl, pyrimidinyl, indolyl, quinolyl, isoquinolyl and quinazolinyl; and

the heterocyclic group formed using the adjacent N is selected from the group consisting of pyrrolidinyl, morpholino, thiomorpholino, N-methylpiperadinyl, pyrazolidinyl, piperidino, piperadinyl, homopiperadinyl, indolyl and isoindolyl;

or a pharmaceutically acceptable salt thereof.

4. (Previously Presented) The compound according to claim 2, wherein

$\text{R}^{2\text{A}}$  represents amino, halogen, formyl, or hydroxy, and  $\text{R}^{3\text{A}}$  represents substituted or unsubstituted lower alkenyl, substituted or unsubstituted lower alkynyl, substituted or unsubstituted lower alkyl (other than hydroxymethyl), or  $\text{NHCOR}^{13\text{A1}}$  [wherein  $\text{R}^{13\text{A1}}$  represents substituted or unsubstituted lower alkyl, substituted

or unsubstituted lower alkenyl, lower alkoxy carbonyl, substituted or unsubstituted aryl, a substituted or unsubstituted heterocyclic group, OR<sup>9A</sup>, or NR<sup>7A</sup>R<sup>8A</sup>; or

R<sup>2A</sup> represents substituted or unsubstituted lower alkenyl, substituted or unsubstituted lower alkynyl, substituted or unsubstituted lower alkyl (other than hydroxymethyl), or NHCOR<sup>13A2</sup> (wherein R<sup>13A2</sup> has the same meaning as defined for R<sup>13A1</sup>), and R<sup>3A</sup> represents substituted or unsubstituted lower alkenyl, substituted or unsubstituted lower alkynyl, amino, substituted or unsubstituted lower alkyl, or NHCOR<sup>13A3</sup> (wherein R<sup>13A3</sup> has the same meaning as defined for R<sup>13A1</sup>),

or a pharmaceutically acceptable salt thereof.

5. (Previously Presented) The compound according to claim 3, wherein R<sup>2B</sup> and R<sup>3B</sup> independently represent substituted or unsubstituted lower alkenyl, substituted or unsubstituted lower alkynyl, amino, halogen, formyl, hydroxy, substituted or unsubstituted lower alkyl, or NHCOR<sup>13</sup>.

6. (Previously Presented) The compound according to claim 2 or 4, wherein R<sup>1A</sup> is hydroxy, or a pharmaceutically acceptable salt of the compound.

7. (Previously Presented) The compound according to claim 3 or 5, wherein R<sup>1B</sup> is hydroxy or a pharmaceutically acceptable salt of the compound.

8. (Previously Presented) A pharmaceutical composition comprising at least compound according to any one of claims 2 to 5, and a pharmaceutically acceptable carrier.

Claims 9- 15 (Cancelled)

16. (Previously Presented) A pharmaceutical composition comprising at least one pharmaceutically acceptable salt according to any one of claims 2 to 5, and a pharmaceutically acceptable carrier.

Claims 17-22 (Cancelled).

23. (Currently Amended) A method for treating a ~~solid tumor~~ pulmonary tumor, comprising the step of administering, to a patient in need thereof, a therapeutically effective amount of the compound or pharmaceutically acceptable salt according to any one of claims 2 to 5.

24. (Previously Presented) A method for enhancing the activity of an antitumor agent for solid tumors, comprising the step of administering a therapeutically effective amount of the compound or the pharmaceutically acceptable salt according to any one of claims 2 to 5, together with said antitumor agent, to a patient in need thereof.

Claims 25- 28 (Cancelled)

29. (Currently Amended) A method for treating a ~~solid tumor~~ pulmonary tumor, comprising the step of administering, to a patient in need thereof, a therapeutically effective amount of the compound or pharmaceutically acceptable salt according to claim 6.

30. (Currently Amended) A method for treating a ~~solid tumor~~ pulmonary tumor, comprising the step of administering, to a patient in need thereof, a

therapeutically effective amount of the compound or pharmaceutically acceptable salt according to claim 7.

31. (Previously Presented) A method for enhancing the activity of an antitumor agent for solid tumors, comprising the step of administering a therapeutically effective amount of the compound or the pharmaceutically acceptable salt thereof according to claim 6, together with said antitumor agent, to a patient in need thereof.

32. (Previously Presented) A method for enhancing the activity of an antitumor agent for solid tumors, comprising the steps of administering a therapeutically effective amount of the compound or the pharmaceutically acceptable salt thereof according to claim 7, together with said antitumor agent, to a patient in need thereof.